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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,388	08/19/2003	Robert A. VanTassel	593/2CIP3CON	6130
1473 7590 05/15/2007 FISH & NEAVE IP GROUP ROPES & GRAY LLP 1211 AVENUE OF THE AMERICAS NEW YORK, NY 10036-8704			EXAMINER KOHARSKI, CHRISTOPHER	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 05/15/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary

Application No.

10/644,388

Applicant(s)

VANTASSEL ET AL.

Examiner

Christopher D. Koharski

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 3-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 8-15 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/21/2003</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Examiner acknowledges the amendment filed 3/01/2007 in which no claims were amended. Currently claims 1-15 are pending for examination with claims 3-7 withdraw from a previous election/restriction (see OA dated 10/12/2006).

Information Disclosure Statement

The information disclosure statement (IDS) that was submitted on 11/21/2003 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

Claim Objections

Claim 13 is objected to because of the following informalities: Regarding claim 13, there is a grammatical error “..wherein the support structure a membrane support..”. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,2 and 8-15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-39 of U.S. Patent No. 6,949,113 and claims 1-9 of U.S. Patent No. 6,652,556. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the current pending application are anticipated by the claims in the cited US patent.

Application claim 1 requires:

Apparatus for permanent placement across an ostium of a left atrial appendage in a patient, comprising: a filtering membrane configured to extend across the ostium of the left atrial appendage and having a permeable structure which allows blood to flow through the filtering membrane but substantially inhibits thrombus from passing therethrough; and a support structure defining a first configuration having a substantially cylindrical shape and a second configuration defining a radially enlarged medial portion to permanently engage the interior wall of the left atrial appendage, wherein the filtering membrane is attached to the support structure extending across the ostium of the left atrial appendage.

While patent (6,949,113) claim 22 requires:

A membrane structure for obstructing an opening in the body of a patient, said membrane comprising: a membrane adapted to be lodged against the opening; prongs adjacent an edge of the membrane extending substantially

outwardly for attaching the membrane to body tissue on the opposite side of the opening from the membrane substantially adjacent the opening for securing the membrane over the opening; and a catheter for minimally invasively inserting the membrane over the opening to block the opening.

While patent (6,652,556) claim 1 requires:

Apparatus for permanent placement across an ostium of a left atrial appendage in a patient, comprising: a filtering membrane configured to extend across the ostium of the left atrial appendage and having a permeable structure which allows blood to flow through the filtering membrane but substantially inhibits thrombus from passing therethrough; and a support structure defining a first configuration having a substantially cylindrical shape and a second configuration defining a radially enlarged medial portion to permanently engage the interior wall of the left atrial appendage, wherein the filtering membrane is attached to the support structure extending across the ostium of the left atrial appendage, wherein the filtering membrane has a composite construction comprising a filtering section and an elastic section, and wherein the elastic section has an opening to accommodate an intervention device.

Thus it is apparent that the application claims are broader than the patent claims and the subsequent patented independent and dependant claims encompass application claims 1, 2 and 8-15. Following the rationale in *In Re Goodman* cited in the preceding paragraph, where Applicant has once been granted a patent containing a claim for the specific or narrower invention, Applicant may not then obtain a second

patent with a claim for the generic or broader invention without first submitting a terminal disclaimer.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 8, 10-13 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Cottenceau et al. (5,375,612). Cottenceau et al. discloses a blood filter.

Regarding claims 1, 2, 8, 10-13 and 15, Cottenceau et al. discloses an apparatus (Figure 1) for permanent placement across an ostium of a left atrial appendage in a patient comprising, a filtering membrane (9) configured to extend across the ostium of the left atrial appendage and having a permeable structure which allows blood to flow through the filtering membrane but substantially inhibits thrombus from passing therethrough, and a support structure (7, 15) defining a first substantially cylindrical shape to a second radial configuration (Figures 13-15) wherein the filtering membrane (9) is attached to the support structure (7, 15) and is capable of crossing the ostium of the left atrial appendage. Cottenceau et al. further discloses a plurality of fingers (Figures 1-4) (near 7) with first, second and medial portion, that expand radially outward with barbed outer members (19, see Figure 2) and are fabricated of stainless (col 4, ln 30-40). Cottenceau et al. discloses a delivery actuation device (43, 45) configured to remotely radially expand the support structure (See Figures 13-15).

Claim Rejections - 35 USC § 102

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Mobin-Uddin (3,540,431). Mobin-Udden discloses a collapsible filter assembly.

Regarding claim 1, Mobin-Udden discloses an apparatus (Figure 4) for permanent placement across an ostium of a left atrial appendage in a patient comprising, a filtering membrane (30) configured to extend across the ostium of the left atrial appendage and having a permeable structure which allows blood to flow through the filtering membrane but substantially inhibits thrombus from passing therethrough, and a support structure (116, 26, 50) defining a first substantially cylindrical shape to a second radial configuration (Figure 3) wherein the filtering membrane (30) is attached to the support structure (7, 15) and is capable of crossing the ostium of the left atrial appendage (Figures 1-6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. - Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9 and 14 are rejected under 35 U.S.C 103(a) as being unpatentable over Cottenceau et al.

Regarding claims 9 and 14, Cottenceau et al. discloses the claimed invention except for the support structure being composed of nitinol or a shape memory material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the materials as claimed by Applicant in order to achieve proper expansion and delivery inside the patient, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Response to Arguments

Applicant's arguments, see remarks and interview, filed 3/01/2007 and 2/28/2007, with respect to the rejection(s) of claim(s) 1,2 and 8-15 under Lesh have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Cottenceau et al. (5,375,612) and Mobin-Uddin (3,540,431).


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 5/11/07


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5/11/07


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